

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Raphael Mechoulam; Natalya M.  
Kogan; Ruth Rabinowitz; and,  
Michael Schlesinger  
Group Art Unit:  
Serial No.: 10/597166  
Confirmation No.: 7062  
Filed: July 13, 2006  
For: THERAPEUTIC USE OF  
QUINONOID DERIVATIVES OF  
CANNABINOID

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir.

RESPONSE TO NOTICE TO FILE MISSING  
REQUIREMENTS UNDER 35 U.S.C. 371 IN THE DO/EO/US

This is in response to the Notice to File Missing Requirements under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US), mailed July 21, 2008.

Applicants submit herewith a copy of the Notice to File Missing Requirements under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US).

Applicants respectfully request that the subject Notification of Missing Requirements be withdrawn for the following reasons:

1. Applicants suggest that the proper fees were timely paid with the filing of the present application in view of the new claim set that was part of the originally filed Section 371 specification. A copy of the claim set intended to be examined appears as a part of the PAIR file history for the subject application. The claim set intended to be examined consists of 41 total claims and no multiple dependent claims. In accordance with M.P.E.P. Section 714.01(e), "Amendments Before First Office Action":

**"Applicants should note, however, that there is no need to file a preliminary amendment to the claims on filing. By making the new claim set part of the originally filed specification, applicant may avoid having to pay an application size fee, as both the specification (including the claims) and any preliminary amendment are used in counting the number of pages for purposes of 37 CFR 1.16(s). The claim set submitted should be the set of claims intended to be examined, and when the claims submitted on filing are part of the specification (on sequentially numbered pages of the specification (see 37 CFR 1.52(b)(5))), no status identifiers and no markings showing the changes need to be used."** M.P.E.P. Section 714.01(e) [Emphasis Added]

Further, M.P.E.P. Section 506, "Completeness of Original Application," pronounces a general principle adopted by the Office regarding Preliminary Amendments at least for filing of non-provisional applications under 37 CFR 1.53(b):

**"Therefore, the Office strongly recommends that applicants file their applications with a specification containing only the desired set of claims, rather than filing the application with a preliminary amendment canceling claims."** M.P.E.P. Section 506 [Emphasis Added]

It appears from the form PTO 1360, "Multiple Dependent Claim Fee Calculation Sheet," which is a part of the subject file history, calculated fees on a claim set other than the one that was submitted with the copy of the specification originally filed with the Section 371 application.

Therefore, Applicants suggest that a Preliminary Amendment is not required in the present application and that the set of claims consisting of 41 total claims, which set is found in the papers of the present application along with the substitute specification, be used for fee calculation purposes. Accordingly, Applicants request that the request for additional claim fees in the Notification of Missing Requirements be withdrawn.

2. Regarding the asserted defective oath or declaration that was filed with the papers of the present application, Applicants used the form PTO/SB/01A promulgated by the Office when an Application Data Sheet is used. A copy of the Application Data Sheet appears as a part of the PAIR file history for the subject application. Therefore, Applicants suggest that the proper form PTO/SB/01A for the oath or declaration has been filed in the subject application. Accordingly, Applicants request that the objection to the form of the oath or declaration in the Notification of Missing Requirements be withdrawn.

3. Finally, the Notification of Missing Requirements states in two bulleted sub-paragraphs on page 2 of 3 that Applicants must submit both a paper copy and computer readable Sequence Listings. In accordance with M.P.E.P. Section 2421.02, "Summary of the Requirements of the Sequence Rules," Applicants suggest that the Sequence Rules should not apply to the subject application.

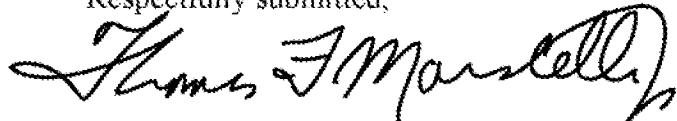
Specifically, M.P.E.P. Section 2421.02 states:

The sequence rules embrace all unbranched nucleotide sequences with ten or more bases and all unbranched, non-D amino acid sequences with four or more amino acids, provided that there are at least 4 "specifically defined" nucleotides or amino acids. The rules apply to all sequences in a given application, whether claimed or not. All such sequences are relevant for the purposes of building a comprehensive database and properly assessing prior art. It is therefore essential that all sequences, whether only disclosed or also claimed, be included in the database." M.P.E.P. Section 2421.02 [Emphasis Added]

Accordingly, Applicants suggest that the subject application does not qualify under the Sequence Rules as requiring a sequence listing. Therefore, Applicants request that the request for the submission of Sequence Listings in the Notification of Missing Requirements be withdrawn.

In conclusion, Applicants request that the Notification of Missing Requirements be withdrawn in its entirety in accordance with the above states reasons and that the application be passed on to the examination phase.

Respectfully submitted,



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Date: August 31, 2008



## UNITED STATES PATENT AND TRADEMARK OFFICE

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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/597,166	Raphael Mechoulam	LUZ033PU
22948	INTERNATIONAL APPLICATION NO.	
MARSTELLER & ASSOCIATES	PCT/IL2005/000053	
P O BOX 803302	I.A. FILING DATE	PRIORITY DATE
DALLAS, TX 75380-3302	01/14/2005	01/15/2004

**CONFIRMATION NO. 7062**  
**371 FORMALITIES LETTER**



Date Mailed: 07/21/2008

### **NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- Indication of Small Entity Status
- Priority Document
- Copy of the International Application filed on 07/13/2006
- Copy of the International Search Report filed on 07/13/2006
- Copy of IPE Report filed on 07/13/2006
- Oath or Declaration filed on 07/13/2006
- U.S. Basic National Fees filed on 07/13/2006
- Priority Documents filed on 07/13/2006
- Power of Attorney filed on 07/13/2006
- Specification filed on 07/13/2006
- Claims filed on 07/13/2006
- Abstracts filed on 07/13/2006
- Drawings filed on 07/13/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of **\$745** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - Applicant submitted what appears to be two different declarations. While each inventor need not execute the same oath or declaration, each oath or declaration executed by an inventor must contain a complete listing of all inventors so as to clearly indicate what each inventor believes to be the appropriate inventive entity. There is no indication whether the inventors are aware that any other inventor was claimed on the above-captioned application except as listed on the page they signed.

**SUMMARY OF FEES DUE:**

Total additional fees required for this application is **\$745** for a Small Entity:

- This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c) Applicant must provide an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application** and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Total additional claim fee(s) for this application is **\$745**

- **\$210** for **4** independent claims over **3**.
- **\$350** for **35** total claims over **20**.
- **\$185** for multiple dependent claim surcharge.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)**

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.

<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

BARBARA A CAMPBELL

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